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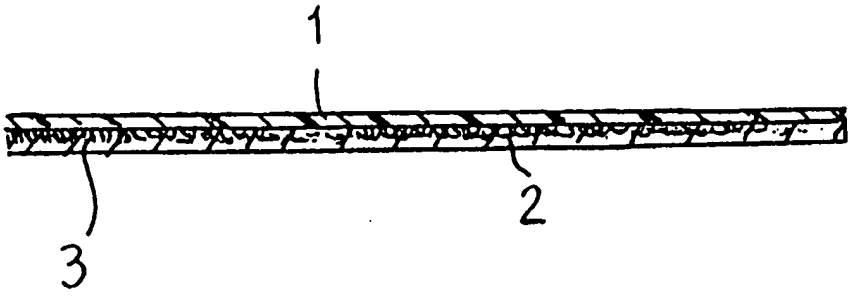

(57) Abstract

The present invention relates to a plastic film dressing or affixing tape for skin application, comprising a plastic film layer (1) coated with adhesive (2) on one side thereof. According to the invention, anchoring elements (3) in particle form are fastened to the plastic film layer (1) over the whole of that side which has been coated with adhesive (2). The adhesive is comprised of an adhesive elastomer which has skin-friendly adhesion properties adn which surrounds the anchoring elements and has a smooth, unbroken surface on the side thereof distal from the plastic film.

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FILM DRESSING OR A TAPE FOR ATTACHMENT TO SKIN.

The present invention relates to a plastic film dressing or an affixing tape for skin applications, comprising a plastic film layer coated with adhesive on one side thereof.

Thin adhesive wound dressings made from a plastic film that is permeable to water vapor, for instance OpSite® (Smith & Nephew, England) or Tegaderm® (3M, USA), include an acrylate-type adhesive or an adhesive that has similar properties. When repeatedly applied and removed, such adhesives are apt to remove with them parts of the upper skin layer (the stratum corneum) and consequently dressings of this nature are liable to result in skin damage. These adhesives also fasten strongly to skin hairs, therewith causing pain and discomfort as the dressing is removed.

Also known to the art is a gauze dressing designated Mepitel®, which is affixed to the skin by means of a very soft adhesive silicone elastomer. Such a silicone elastomer has skin-friendly adhesive properties and is much more gentle to the skin than the aforesaid adhesives. Neither does it tend to strip away parts of the stratum corneum as it is removed. A person wearing such a dressing will not experience discomfort or pain as the dressing is removed. The adhesiveness of the silicone elastomer is not impaired by removal of the dressing, and the dressing can therefore be removed and replaced several times.

Consequently it would be beneficial if the adhesives used with plastic film dressings could be replaced with an adhesive elastomer that has adhesive characteristics similar to those of the silicone elastomers used with Mepitel®, particularly when the dressing is to be applied to sensitive skin. One serious problem in this regard is that such elastomers have been found to adhere to the skin with the same strength as that to which they adhere to the plastic film, and consequently there is a serious risk of the elastomer layer, or large parts thereof, remaining on the skin when attempting to remove the dressing.

One object of the present invention is to solve this problem and to provide a functional film dressing which includes a layer of soft, adhesive elastomer.

This object is achieved in accordance with the invention by means of a dressing or affixing tape for skin applications which includes a plastic film layer that is coated with adhesive

on one side thereof and which is characterized in that anchoring elements in particle form are fastened to the plastic film layer over the whole of that side thereof which is coated with a fully or partially covering layer of adhesive; and in that the adhesive is comprised of a soft, adhesive elastomer which surrounds the anchoring elements and which has a smooth, unbroken surface on the side thereof distal from the plastic film. Because the adhesive elastomer is affixed to the plastic film via the anchoring elements, the elastomer will be anchored more strongly to the film than would otherwise be the case, so as to avoid the risk of the elastomer remaining on the skin when the dressing is removed therefrom. The anchoring elements affixed to the plastic film do not reduce the flexibility and stretchability of the plastic film to any appreciable extent, these properties being important in some types of dressing.

In one preferred embodiment of the invention, the anchoring elements are comprised of short fibres and the adhesive elastomer is a silicone elastomer.

In one variant, the anchoring elements are comprised of particles.

The invention will now be described with reference to the accompanying drawings, in which

Figure 1 is a schematic cross-sectional view of a plastic film dressing or affixing tape for skin applications, according to one preferred embodiment of the invention; and

Figure 2 illustrates a softnesss measuring instrument.

The wound dressing illustrated in the figure is comprised of a plastic film layer 1 whose underside is coated with a layer of adhesive elastomer 2. Anchoring elements 3 in the form of short, loose fibres are affixed to the plastic film over the whole of its undersurface. The anchoring elements 3 have been affixed to the underside of the layer 1 prior to applying the elastomer layer 2 and function to increase the surface area with which the elastomer comes into contact. As a result, the elastomer will adhere to the film layer 1 carrying the anchoring elements 3 with a greater force than that with which it adheres to the skin,

therewith enabling a skin dressing of this kind to be removed safely from the skin without risk of the elastomer releasing its attachment with the film layer and remaining on the skin.

In order to ensure that the flexibility and stretchability of the film layer will not be reduced appreciably as a result of applying the anchoring elements, said anchoring elements will preferably be affixed to the plastic film in a discrete fashion, i.e. mutually unconnected. The anchoring elements will also preferably be distributed relatively uniformly over the underside of the plastic film, so as to avoid local variations in the adhesion of the elastomer to the plastic film.

The anchoring elements 3 may comprise cellulose fibres measuring from 0.1-3 mm in length. Such fibres can be fastened to the film layer 1, by first providing the layer with a glue coating and then scattering or strewing the loose fibres over said glue layer, e.g. by air laying. Fibres other than cellulose fibres may, of course, be used, for instance viscose fibres, cotton fibres, polyester fibres, polyamide fibres and like fibres.

Alternatively, the anchoring elements may be affixed to the film by flocculation or extrusion for instance.

Although fibres are preferred as anchoring elements, there may be used, in principle, all types of particle material that can be fastened to plastic film. By particle material is meant in this document in addition to the aforesaid fibre material all material that consists of individual bodies having a size smaller than 10^{-3} mm^3 regardless of the shape of said bodies. For instance, the particle material may comprise plastic granulate, silicone dioxide, silicone or the like. The elastomer layer shall have a thickness that exceeds the largest dimension of the particles, so as to ensure that all particles will be enclosed regardless of the position in which said particles have been affixed to the film layer.

The elastomer layer is preferably formed by an adhesive silicone elastomer retailed under the designation Silgel 612 by Wacker Chemie GmbH, Germany. It will be understood, however, that other soft, adhesive silicone elastomers, hydrogels or soft adhesive hot melt glue can be used.

The wound dressing may, of course, be perforated, especially if it includes an overlaying absorbent pad.

It shall also be possible to sterilise the dressing by means of some conventional sterilisation method, e.g. b-sterilisation, steam sterilisation or sterilisation with ethylene oxide.

The expression "skin-friendly adhesion" is used in this document to characterise a particular form of adhesion exhibited by the soft, adhesive elastomers suited for use with the invention.

Different types of self-adhering glues having relatively similar properties are used normally on adhesive dressings and surgical plasters of different kinds. A common feature of the glues normally used is that they adhere to the outermost layer of dead skin cells (stratum corneum) so firmly that a number of layers of these cells will be stripped from the skin by the glue as the adhesive dressing is removed. The glues used at present are most often acrylate-type glues, although hot melt glues and polyisobuthylene glues are also often used. In the case of skin-friendly glues, the penetration - which constitutes a measurement of softness - shall lie within the range of 7-20 mm, whereas corresponding values for those glues that are normally used with adhesive dressing are less than 3 mm. Penetration is measured by means of a method based on ASTM D 937 and D 51580. Certain modifications are made. The equipment used is a penetrometer PNR 10, Sommer & Runge KG, Germany. A test body weighing 62.5 g and comprising a cone weighing 15 g and bearing article number 18-0122 and a rod weighing 47.5 g and bearing the article number 18-0042 was placed in the penetrometer vertically above a cylindrical cup containing the material to be tested, with the apex of the cone touching the surface of the test material. The test body was then allowed to fall freely down into the cylindrical cup. The extent to which the test body had penetrated the test material was measured after a time lapse of 5 seconds. The cylindrical cup had a diameter of 50 mm and a height of 30 mm. The cup was filled with test material to a level of 25 mm.

The soft elastomers having skin-friendly adhesive properties and used in accordance with the present invention had considerably weaker adhesive bonds to the skin than the glues normally used with adhesive dressings. Consequently, elastomers that have skin-friendly adhesive properties leave the stratum corneum essentially intact when dressings containing

such elastomers are peeled or pulled away. In spite of the weaker adhesive bonds, the elastomers nevertheless create secure and positive adhesion, i.e. there is small risk of the dressing loosening by itself, by virtue of the fact that the softness of the elastomer causes it to pass down into the skin and therewith provide a large effective contact surface. The softness of the elastomer also results in a large energy build-up in the elastomer and its carrier when removing the dressing, which also results in more positive adhesion to the skin.

An experiment was carried out on ten voluntary test persons with the intention of measuring the stripping effect, by which is meant the extent to which the surface of the dressing became covered with cells as a result of stripping-off the dressing. Four different types of plaster/dressings were used, these being Duoderm®, OpSite®, Leukopore® and an elastomer-coated (200 g/m^2) non-woven tape. The soft elastomer having skin-friendly adhesive properties was a silicone type elastomer. Three test samples of each product type were applied to each test person and left in place for 24 hours. The stripping effect was recorded, by coloring the stratum corneum cells present on the surface of the removed dressings selectively with toluidine, whereafter the percentage of the surface covered by cells was determined.

The results are evident from the table below:

Plaster/dressing	number of dressings with stripping within the range		
	<1%	-10%	3 11%
Duoderm®	0/30	0/30	30/30
OpSite®	0/30	0/30	30/30
Leukopore®	10/30	16/30	4/30
silicone tape	27/30	3/30	0/30

In order to be "skin-friendly adhesive", an adhesive dressing shall have a stripping effect of maximum 10% in the case of normal skin.

Because a dressing that includes a skin-friendly adhesive elastomer will only carry with it a very limited number of stratum corneum cells when the dressing is removed, the surface of

the elastomer layer will be relatively unchanged after removal of the dressing. This enables a dressing of this nature to be re-applied, since it adhesiveness has not been impaired to any appreciable extent. The adhesive surface of a dressing which pulls stratum corneum cells from the skin will be substantially covered with the cells subsequent to its removal. This means that dressings of this nature will fail to stick to the skin when attempting to re-apply the dressings. Duoderm®, OpSite® and Leukoporev® lose from 70 to 100% of their adhesiveness, whereas skin-friendly adhesive dressings lose less than 10%.

In order for an adhesive dressing or adhesive plaster to function effectively, the force with which it adheres to the skin must exceed the load to which the dressing or plaster is subjected during normal use. It has been found that there is generally required in this respect an adhesive force which exceeds 0,5 N measured when peeling or stripping from the skin a tape measuring 25 mm in width and angled at 135°, so that the danger of the dressing loosening by itself will not be unacceptably high. The adhesive force will preferably exceed 0.8 N/25 mm.

The adhesive force of Duoderm®, OpSite® and Leukopore® was measured at 1.2, 2.2 and 0.8 N/25 mm respectively with tape applied to the backs of healthy test persons and left in place for 24 hours. The silicone tape used in the stripping test above had a skin adhesion strength of 1.5 N/25 mm.

The plastic film will suitably comprise polyurethane, although other plastics, such as silicone plastic, may be used.

Claims

1. A plastic film dressing or affixing tape for skin applications comprising a plastic film layer (1) coated with adhesive (2) on one side thereof, characterized in that anchoring elements (3) in particle form are fastened to the plastic film layer (1) over the whole of that side which has been coated with adhesive (2); and in that the adhesive is an adhesive elastomer that has skin-friendly adhesion properties and that surrounds the anchoring elements and has a smooth, unbroken surface on that side distal from the plastic film.

2. A dressing according to Claim 1, characterized in that the anchoring elements (3) are comprised of short fibres.

3. A dressing according to Claim 1, characterized in that the anchoring elements are comprised of particles.

4. A dressing according to any one of Claims 1-3, characterized in that the adhesive elastomer (2) is a silicone elastomer.

5. A dressing according to any one of Claims 1-4, characterized in that the dressing is perforated.

6. A dressing according to Claim 5, characterized in that it includes an absorbent pad.

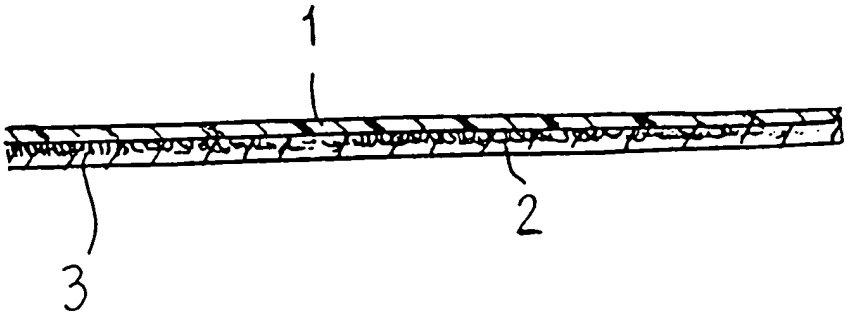
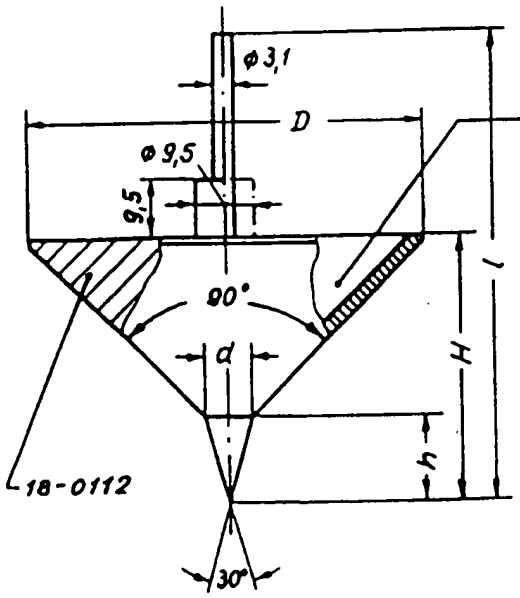


FIG. 1



Nr.	ϕD	H	ϕd [mm]	h	l
18-0101	65	44	8,4	15	77
18-0102					
18-0112	69,35	47			82
18-0121	65	44			77
18-0122					
18-0123					
18-0131	16,3	11,6	2,1	3,8	39,5
18-0141	32,5	22	4,2	7,5	37,5

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/00904

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61L 15/26, A61L 15/58
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 8705206 A1 (MÖLNLYCKE AB), 11 Sept 1987 (11.09.87) --	1-6
A	WO 9014109 A1 (SMITH & NEPHEW PLC), 29 November 1990 (29.11.90) --	1-6
A	WO 9609076 A1 (MÖLNLYCKE AB), 28 March 1996 (28.03.96) --	1-6
A	WO 9742985 A1 (SCA MÖLNLYCKE AB), 20 November 1997 (20.11.97) --	1-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 August 1999	01 -09- 1999
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Jack Hedlund/EÖ Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

Information on patent family members

02/08/99

International application No.
PCT/SE 99/00904

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